

### REMARKS

In the application, Claims 1-21 are pending and Claims 1-5, 8-12 and 15-19 are rejected. After due consideration of the Examiner's comments, the Claims 1 and 8 have been amended as set forth above. In view of these amendments, Applicants submit that the application is now in a condition for allowance and requests that the Examiner issue a notice of allowance.

#### Rejection under §102

The Examiner maintains his rejection of Claims 1, 4, 5, 8, 11, 12, 15, 18, and 19 under 35 U.S.C. §102(b) as being anticipated by Bassett et al. After due consideration of the Examiner's comments, an added limitation of a quality control process has been added to Claims 1 and 15, and an added limitation of a quality control module has been added to Claim 8. The limitations relating to quality control are supported in the specification as indicated in the table below and in Figures 8 and 10.

Page:Line	Relevant Text
16:1-3	DW 220 is loaded with sample, gene annotation, and expression data from a staging area where the data is integrated after passing data consistency and quality validation.
25:17-20	In one embodiment of the present invention, the CPG, CAG, CPS, and CAP operations may be varied using an additional threshold, T, for defining the gene expression consistency in terms of the minimum number of samples out of the total number of samples in 5, for which the genes are present or absent.
28:2-3	DMS 210 provides support for various sample acquisition and quality control protocols, . . .
28:9	DMS 210 manages gene expression experiment, QC/QA, and process data.
28:19-23	DMS 210 integrates seamlessly the sample data management system with the GeneChip LIMS and a Chip QC module, thus ensuring data consistency across and efficient data flow through component data management systems. The Chip QC component is used for detecting chip image defects using both image software and manual visual analysis and for masking the probes affected by these defects.

39:17-22	Additional integration tasks include the masking of defective gene fragments on chips out of experimental data and enforcement of the sample completion constraint. The chip quality control identifies defective spots in the scanned images that should not be incorporated in cell and chip analyses. The quality control process reports the gene fragments per experiment that are affected by image defects, in files that are transferred to the pre-staging area. These files are used to mask out expression data points by turning the Present/Absent (P/A) call to Unknown (U)
40:3-6	The process of getting all chips per sample in order to make a complete expression vector is called sample completion. A preferred embodiment of the present architecture allows enforcement of sample completion at staging, . . .

Bassett et al. does not teach a system that performs a quality control function. At page 53, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph, Bassett et al., quoting from a book by Berry and Linoff entitled *Data Mining Techniques for Marketing Sales and Customer Support* (John Wiley & Sons, New York, 1997), list requirements drawn from other fields, including that the “[d]ata in the warehouse have already been cleaned and verified. Data from multiple sources have been integrated. A single data model ensures that similarly named fields have the same meaning” In Bassett et al., the data are already cleaned and verified by some disclosed means. They then go on to state that “although these goals have largely been achieved for sequence, structure and bibliographic data, . . ., much work needs to be done to achieve similar results for gene expression data.” They propose a standard for annotated gene expression data in a public database, but provide no real discussion of quality criteria other than suggesting that one would ideally repeat an experiment a sufficient number of times to determine variance (page 54, 1<sup>st</sup> col. 3<sup>rd</sup> paragraph). In contrast, the claimed invention provides automated procedures for performing quality control operations on gene expression data before integrating the data into the data warehouse to ensure that unreliable or defective data will not be loaded.

Claim 8 has been amended by adding the element of the data management system, which incorporates the quality control module. Support for this addition is provided in the table above.

Rejection under §112

The Examiner rejects Claims 1, 8, and 15 under 35 U.S.C. §112, 1<sup>st</sup> paragraph as failing

to comply with the written description requirement. Specifically, the Examiner states that “staging of gene expression data for storage” and “staging comprises linking gene expression measurements in the gene expression database with sample data in the clinical database and information in the fragment index database” are not directly taught in the specification.

Applicants respectfully submit that identified claim limitations relative to staging and the staging database are fully supported in the specification at least at the locations identified in the table below. The staging reference in each passage is underlined. The staging process step is also illustrated in Figure 10.

Page:Line	Relevant Text
16:1-6	DW 220 is loaded with sample, gene annotation, and expression data from a <u>staging area</u> where the data is integrated after passing data consistency and quality validation.
29:2-6	Still referring to Figure 2, in accordance with one embodiment of the present invention, DMS 210 directs the data generated by the GeneChip LIMS as follows: the DAT, CEL, CHP files are sent to Archive 230; the gene expression data, in relational AADM format, and the QC data are transferred to the DW 220 <u>staging area</u> where the necessary data integration, transformation, validation, and correction are performed before loading the data into DW 220.
33:4-7	The totality of these data streams defines the interface between the relational database management system and the relational database for storing and retrieving biological information. Specifically, all these data streams feed into a <u>staging area</u> where a warehouse building processes take place, i.e., validation, transformation and integration of the data.
34:6-9	In another preferred embodiment of the present invention, gene expression integration is also provided. Gene expression integration refers to the integration of experimental data with clinical and public gene data (Fragment Index). Gene expression integration is a task performed at the <u>staging database</u> .
39:2-3	Another important function of the <u>staging database</u> is expression data integration, i.e., linking the expression data with the clinical database and the fragment index.

Rejection under §103

The Examiner rejects claims 1-5, 8-12 and 15-19 under 35 U.S.C. §103(a) as being unpatentable over Bassett et al. as applied to claims 1, 4, 5, 8, 11, 12, 18 and 19 in further view of Gopalikrishnan et al. The latter reference is cited for its disclosure of a star relational schema.

It is respectfully submitted that because Gopalikrishnan et al. fail to teach both an automated quality control process/module and a staging process/module as now claimed, it does not provide the teachings that are missing from Bassett et al. that would be needed to teach or suggest Applicants' invention. Accordingly, Applicants respectfully submit that the combination of Gopalikrishnan et al. and Bassett et al. cannot render the claimed invention obvious.

Replacement Drawings

Being filed herewith are replacement drawings for Figures 1, 3, and 5-10, which are being submitted to provide clean drawings with even lines and legible text, and without shading or handwritten components. The replacement drawings are reconstructions of the drawings as originally filed. Apart from correction of a spelling error in Figure 10, no changes have been made, and no new matter is introduced.

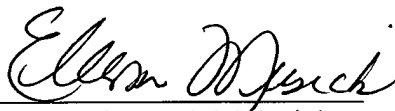
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CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that all bases for rejection have been addressed and overcome such that the amended claims are allowable over the prior art and that the specification adequately supports and describes the changes made. Accordingly, Applicants respectfully request that the Examiner withdraw all rejections set forth in the Office Action and issue a notice of allowance for all claims now in the application.

Respectfully submitted,

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